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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/518,915 | 12/23/2004 | Kiichiro Yano | 053466-0391 | 7057 |
| 22428 | 7590 | 12/19/2008 | EXAMINER | |
| FOLEY AND LARDNER LLP | | | CLARK, AMY LYNN | |
| SUITE 500 | | | ART UNIT | PAPER NUMBER |
| 3000 K STREET NW | | | | 1655 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|------------------------------------|
| Office Action Summary | Application No. 10/518,915 | Applicant(s) YANO ET AL. |
| | Examiner Amy L. Clark | Art Unit 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4 and 6-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date 09/11/2008
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2008 has been entered.

Claim Rejections - 35 USC § 112

Claims 4 and 6-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the claims 4 and 6-18, Applicant claims, "da zao (*Zizphus jujube* Miller var. *inermis* Rehder), ginseng (*Panax ginseng* C. A. Meyer), roman chamomile (*Anthemis nobilis* Linne), chlorella (*Chlorella vulgaris* Chick), coicis semen (*Coix lacryma-jobi* Linne var. *ma-yuen* Stapf), and silk (*Bombyx mori* Linnaeus)", thereby introducing Latin names that were not previously disclosed in the originally filed specification, which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept

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because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for the following Latin names: *Zizphus jujube* Miller var. *inermis* Rehder, *Panax ginseng* C. A. Meyer, *Anthemis nobilis* Linne, *Chlorella vulgaris* Chick, *Coix lacryma-jobi* Linne var. *ma-yuen* Stapf or *Bombys mori* Linnaeus. The specification merely provides the following terms: da zao, ginseng, roman chamomile, chlorella, coicis semen and silk. This is not sufficient support for the newly added Latin names: *Zizphus jujube* Miller var. *inermis* Rehder, *Panax ginseng* C. A. Meyer, *Anthemis nobilis* Linne, *Chlorella vulgaris* Chick, *Coix lacryma-jobi* Linne var. *ma-yuen* Stapf or *Bombys mori* Linnaeus. This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claim Rejections - 35 USC § 102

Claims 4, 11, 12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlen et al. (B, 4,707,354).

Garlen teaches a method for treating skin comprising covering said skin with a layer of a sunscreen, protectant, moisturizing, dermatological composition consisting essentially of a formulation comprising less than 1 wt % silk powder (See claim 8).

Garlen further teaches that the method for administration of such compositions to human skin to provide rehydration and nearly complete screening of cancer-causing actinic radiation (See abstract) and protects mature skin from cell damage and dehydration due to exposure to sunlight (See "Field of the Invention"), which reads on "inhibits photoaging" and "inhibiting wrinkles caused by photoaging", since blocking sunlight inhibits photoaging and inhibits wrinkle formation caused by photoaging.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 4, 7, 8, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sei et al. (S, JP 2002/128651 A, Translation provided herein), in view of Andre-Jean et al.(T, JP 07-145067 A, Translation provided herein).

Sei teaches a photoaging inhibitor (See abstract(that has an anti-aging effect and demonstrates a high improvement effect to wrinkles (See paragraph 0077) in the form of a topical composition for administration to the skin comprising ginseng extract in an amount of 0.00001 - 10 mass %, or 0.0001 to 5% (See paragraph 0008), coix seed

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extract, a seaweed extract (See paragraph 0037), chamomile extract (See paragraph 0012) in an amount of 0.0001 to 3% (See paragraph 0018), and a zizyphi fructus extract (See paragraph 0039). Sei further teaches that the skin care composition is administered, topically, to a mouse and that the skin care composition is administered, *in vitro*, to human skin cells (See Examples paragraphs 0041-0063).

Andre-Jean teaches a cosmetic composition for treating skin comprising 0.1-15 wt.% hydroglycol extract of alga such as Chlorella (See abstract). Brin further teaches that the therapeutic method by these cosmetics protects the skin and hair from the exteriors, such as an oxidizer, sunrays, and a staining agent, against the element which does adverse action, maintains the organization of the skin or hair, and aims at improving the quality of the skin (See paragraph 0038), which reads on inhibiting photoaging. Brin further teaches examples of administering the cosmetic composition to the skin (See Example 1 beginning with paragraph 0040).

The method of using the referenced composition is not expressly taught as a method of inhibiting wrinkles caused by photoaging. However, the instantly claimed process is a **one-step process** of applying to skin a composition comprising .1-15 wt.% hydroglycol extract of alga such as Chlorella. Thus, the functional effect of protecting keratinous fiber from extrinsic damage is intrinsic to the method of using the composition taught by Brin particularly since the amount of an extract of chlorella administered to the skin falls within the range claimed by Applicant.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Sei by administering a

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composition comprising da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract, which are all ingredients that have the same functional effect of inhibiting photoaging and inhibiting wrinkles caused by photoaging. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract for their known benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging since each claimed ingredient is well known in the art for the same purpose, as useful for weight loss and for the following reason:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract, are useful for inhibiting photoaging and inhibiting wrinkles caused by photoaging, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective for inhibiting

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photoaging and inhibiting wrinkles caused by photoaging. Thus, combining them flows logically from their having been individually taught in prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to combine da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract to provide a beneficial composition for the expected benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging because at the time the invention was made, the instantly claimed ingredients da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract were known to be useful for inhibiting photoaging and inhibiting wrinkles caused by photoaging, and since the ingredients and mode of administering the ingredients, which are one and the same as those claimed by Applicants, was known in the art at the time the invention was made. Thus the combined composition of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract would have been expected to be even more effective for inhibiting photoaging and inhibiting wrinkles caused by photoaging because the claimed ingredients were all useful for this purpose, as clearly taught by the above references.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following ingredients for inhibiting photoaging and inhibiting wrinkles caused by photoaging to gain the benefits of individual components as part of a composition for inhibiting photoaging and inhibiting wrinkles caused by photoaging: da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract,

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and silk extract, to provide a beneficial composition for the expected benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging because at the time the invention was made, these ingredients were well known promoting weight loss.

Moreover, it would have been obvious to one of ordinary skill in the art, one would have been motivated and one would have had a reasonable expectation of success at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract because at the time the invention was made, da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract were known to be useful for promoting inhibiting photoaging and inhibiting wrinkles caused by photoaging and the references provided herein teach amounts of the ingredients claimed. Therefore, adjusting the amount of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract would have been obvious to enhance the effect of these ingredients. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence

to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655

Amy L. Clark
AU 1655